

AseptiSac™ A Autoclavable Beta Bags

mdi AseptiSac™ A autoclavable single use bags with beta port are designed for transfer of sterile components into isolators or removal of aseptic waste out of isolators.

These fits onto alpha port on isolators, while maintaining the sterile contamination free environment.

Sizes Available: Beta Port

- 190 mm

Materials of Construction

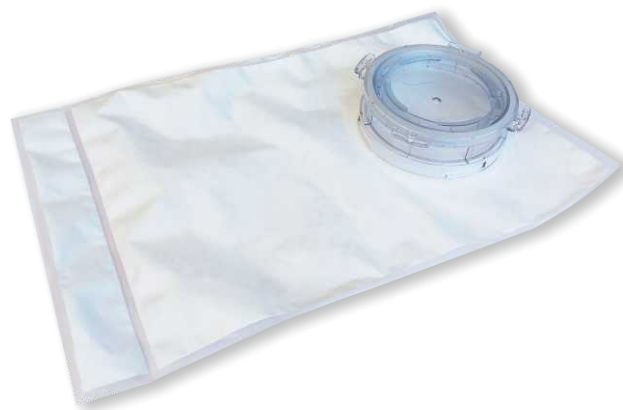
Flange and Cover		High temperature polycarbonate
Beta Seal		Platinum cured silicone
O-Ring		Platinum cured silicone
Weld Ring		High density polyethylene (HDPE)
Bag layers	Top	High density polyethylene (HDPE)
	Bottom	Tyvek

Applications

Aseptic manufacturing of drug products

Unique Performance Advantages

- Removable/reusable handle system
- Fast and easy contamination free transfer
- Increased flexibility and reduced manufacturing time
- Minimize validation costs
- No decontamination
- No cleaning validation
- Minimized manual intervention



Specifications

Sterilization by autoclaving

121°C for 30 minutes, 1 cycle

Bioburden Levels

Bioburden level is < 1000 cfu/bag as per ISO 11737-1

Bacterial Endotoxin Levels

Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amoebocyte Lysate (LAL) test as per USP <85>

Fiber Release

Passes test as per USP and comply with USFDA Title 21 CFR Part 210.3(b)(6) for fiber release

Particle Release

Complies with USP <788> test for particulate matter in injections